

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) Chemical mixtures that are distributed directly to an incinerator for destruction or directly to an authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700-22; persons distributing the mixture to the incinerator or recycler must maintain and make available to agents of the Administration, upon request, such documentation for a period of no less than two years.

(2) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, and temporary protective coatings.

(3) Iodine products classified as iodophors that exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e., povidone-iodine), undecoylium chloride iodine, nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate.

(4) Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amiodarone.)

(e) The Administrator may, at any time, terminate or modify the exemption for any chemical mixture which has been granted an exemption pursuant to the concentration limits as spec-

ified in paragraph (c) of this section or pursuant to the category exemption as specified in paragraph (d) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exemption for a product or group of products for which evidence of diversion has been found, as well as the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may modify any part of the criteria for exemption as specified in paragraphs (c) and (d) of this section upon evidence of diversion or attempted diversion. In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER a final order.

[68 FR 23204, May 1, 2003, as amended at 69 FR 74971, Dec. 15, 2004; 71 FR 60826, Oct. 17, 2006; 72 FR 20047, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40745, July 25, 2007]

§ 1310.13 Exemption of chemical mixtures; application.

(a) The Administrator may, by publication of a Final Rule in the FEDERAL REGISTER, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in

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the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture and:

(i) If the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared; and

(ii) If a group of mixtures (*e.g.* formulations having identical function and containing the same listed chemical(s)), the information required in paragraph (c)(3)(i) of this section and a brief narrative of their use.

(4) (i) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or

(ii) If a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.

(5) (i) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and

(ii) If a group of mixtures, how the group's properties differ from the properties of the listed chemical.

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria set forth in paragraph (a) of this section.

(7) A statement that the applicant accepts the right of the Administrator

to terminate exemption from regulation for the chemical mixture(s) granted exemption under this section.

(8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(e) Within 30 days after the receipt of an application for an exemption under this section, the Administrator will notify the applicant of acceptance or rejection of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is granted, the applicant shall be notified in writing and the Administrator shall issue, and publish in the FEDERAL REGISTER, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

(f) The Administrator may, at any time, terminate or modify an exemption for any product pursuant to paragraph (e) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exempt product or group of exempt products for which

evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(g) A manufacturer of an exempted chemical mixture shall notify DEA in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new applica-

tion will be required only if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer seeking exemption must apply for such an exemption. A formulation granted exemption by publication in the FEDERAL REGISTER will not be exempted for all manufacturers.

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt chemical mixtures for the purposes set forth in this section and are exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822, 823, 830, 957 and 958):

EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name ¹	Form	Date
[Reserved]			

¹ Designate product line if a group.

[68 FR 23204, May 1, 2003, as amended at 75 FR 10681, Mar. 9, 2010]

§ 1310.16 Exemptions for certain scheduled listed chemical products.

(a) Upon the application of a manufacturer of a scheduled listed chemical product, the Administrator may by regulation provide that the product is exempt from part 1314 of this chapter if the Administrator determines that the product cannot be used in the illicit manufacture of a controlled substance.

(b) An application for an exemption under this section must contain all of the following information:

(1) The name and address of the applicant.

(2) The exact trade name of the scheduled listed chemical product for which exemption is sought.

(3) The complete quantitative and qualitative composition of the drug product.

(4) A brief statement of the facts that the applicant believes justify the granting of an exemption under this section.

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Federal, Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit additional documents or written statements of fact